

REMARKS

Claims 1-22 were pending in this application. Claim 1 has been amended. Claims 23 and 24 have been added. No new matter has been added.

ARGUMENTS

Claims 1-4, 6-8, 11, 16-17, 19 and 21 have been rejected under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 4,739,758 to Lai et al. ("Lai").

Regarding Claim 1, the Examiner states that Lai teaches an expandable intragastric balloon comprising an outer casing and an inflation chamber within the casing, both of which are flexible enough to pass from a reduced-volume shape into the stomach of a patient. In point of fact, Lai discloses an intragastric balloon comprising an inner balloon skin 22 and an outer layer of "thin layer of silicone rubber [21 which] may be bonded to the outer surface of the balloon to provide additional bio-compatibility with the patient" (Lai, col. 1, lines 65-68, emphasis added). See, also, col. 3, lines 41-45. The purpose of the silicone rubber outer layer is for bio-compatibility, not creation of an independently expandable an inner chamber. In fact, since the inner and outer layers are bonded to each other both in the reduced-volume configuration (see Lai Fig. 5) and in the expanded configuration (see Lai Fig. 2 and Fig. 3), there can be no substantially separate and independent deployable/expandable inner structure which is distinct from the outer structure.

Claim 1 has been amended to reflect that the claimed intragastric balloon comprises an outer casing structure separate and independent from the forming means (e.g., the inner pouch structure). For support, see, for example, ¶¶0037, 0047 and 0050. In the reduced volume configuration, as represented in Fig. 2 of the present application, the outer casing and the forming means are separated and substantially independent, i.e., they are moving independently of each other. In the expanded configuration, the forming means exert stress on the outer casing but they are only touching each other, not bonded to each other. It is more appropriate to consider in Claim 1 (and also new Claims 23-24) the outer casing and the forming means as two separate

structures rather than layers, each structure having a distinct purpose and being able to move independently with respect to one another.

Thus, the claimed invention is not shown or disclosed by Lai, and Lai does not anticipate the claimed invention.

Regarding the rejections under §103, the Examiner appears to consider Lai as the most relevant art as the technical problem to solve is the same as addressed in the present application, namely, to provide a durable intragastric balloon mechanically strong and protected from external stresses and whose forming and expansion are simplified and fast. To solve this technical problem, Lai discloses an intragastric balloon comprising an inner layer having an inflation chamber, and an outer layer of silicone rubber wherein the two layers are bonded to each other. Co-joined layers may have some disadvantages, such as, but not limited to, formation of folds on the outer casing during the expansion or interferences between the outer casing and the inflation chamber, both due to the connection between the two layers.

In contrast, the solution provided by the presently claimed combination incorporates two separate and independent structures. These structures form two separate chambers, one contained within the other. This solution makes it possible to prevent or substantially reduce the outer casing from interfering with the inflation of the inner inflation chamber and to prevent the formation of folds on the outer casing. Separate and independent structures for use in an inflatable balloon for intragastric use is not disclosed, taught or suggested by Lai; therefore, Lai does not itself make out a *prima facie* case of obviousness of the present claims.

Regarding the rejection of Claims 5, 12-14 and 22, the combination of Lai and Gau do not provide the presently claimed combination. Gau's use of silicone for a single layer intragastric balloon and Lai's silicone rubber outer coating layer do not together suggest a double outer casing—inner pouch structure where each structure is separate and independent.

Regarding the rejection of Claims 9-10, the combination of Lai and Garren do not provide the presently claimed combination. Analogous to the argument above with respect to Gau, Garren's use of polyurethane and Lai's bonded-layer balloon do not make out a *prima facie* case

of obviousness of the presently claimed invention because there is no motivation by the references, either singly or in combination, to provide a double chamber structure.

Regarding the rejection of 15, 18 and 20, if one of ordinary skill in the art combined the separate chamber construction of Paganon in the balloon of Lai, one would not obtain the presently claimed invention, but rather, an intragastric balloon comprising at least two flexible bags, inflated with different fluid, and the external bag comprising two layers. Thus, the presently claimed invention is nonobvious over the cited combination.

For the above and other reasons, Applicant submits that amended Claim 1, as well as the claims dependent therefrom, is patentable over the cited prior art.

New Claim 23 highlights the structure creating the inflation chamber. New Claim 24 highlights the two separate chambers and expandable volumes created by the two structures. Support can be found, for example, in Fig. 2.

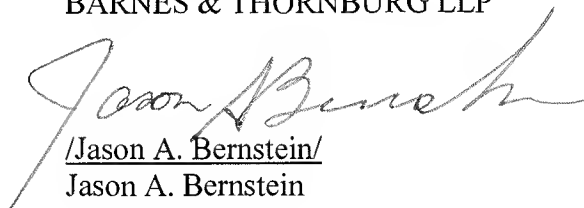
CONCLUSION

Applicant submits that the present application is in condition for allowance and respectfully requests such action. If the Examiner has any questions that can be answered by telephone, please contact the undersigned attorney of record at the telephone number listed below.

It is requested that, if necessary to effect a timely response, this paper be considered a Petition for an Extension of Time sufficient to effect a timely response with the fee for such extensions and shortages in other fees being charged, or any overpayment in fees being credited, to the Account of Barnes & Thornburg LLP, Deposit Account No. **50-4913**.

Respectfully submitted,

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